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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,206	02/09/2001	Michael Fritz	RDID0028US	5556

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,206	FRITZ ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41,68-73 and 76-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41,68-73 and 76-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on March 14, 2006 has been entered.

Status of the Application

2. Claims 36-41, 68-73, 76-79 are pending and claims 1-35, 42-67, 74-75 are cancelled. New claims 76-79 are added. All amendments and arguments have been thoroughly reviewed and deemed not persuasive for the reasons that follow. The rejections are rewritten to include the limitations in the new claims. This action is made Non-final.

Objection to the Specification

3. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least page 22 and 24) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.).

page 22 and 24 of the instant specification contains several sequences (having more than 10 nucleotides) which are not identified by SEQ ID No. (see MPEP 2422.03). Examiner notes that these sequences are neither represented by a paper copy of sequence listing nor in a computer readable form.

Appropriate correction is required.

4. The following rejections are made in the previous office action and are re-written to include the limitations in the new claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 36-41, 69-73, 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (US 5,593,838).

Zanzucchi et al. teach an apparatus of 36, 70, 77-78 for detecting nucleic acids in a sample (see col. 2, line 21-43, col. 4, line 15-62, Fig. 2) comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 4, line 15-40, line 51-54, col. 5, line 50-60, Fig. 2-3, col. 6, line

51-58, Fig. 1B. wherein, Fig. 2-3 indicates a binding space (36) and Fig. 1B. indicates the collection of impurities);

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 4, line 40-42, Fig. 1B and Fig. 2, indicating a part of a binding space includes an amplification space (40), said binding space and amplification space are connected through capillary channel (38));

(c) a detection space for detecting the nucleic acids (see col. 4, line 42-51, Fig. 2 indicating detection space (44)).

With regard to claims 37, 73, Zanzucchi et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 15-33, col. 10, line 66, col. 12, line 42-60, col. 2, line 40-60);

With regard to claims 39, 41, 76, Zanzucchi et al. teach that the amplification space comprises capillary space made up of glass (see col. 6, line 15-25, the microlaboratory disc comprising amplification space is made up of glass, which acts as semiconductor, also see Fig. 5b, and col. 8, line 35-52, indicating complete capillary space is covered or made up of glass);

With regard to claim 40, 79, Zanzucchi et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal layer (see col. 6, line 59-67, metal layer indicates a heatable element);

With regard to claims 38, 69, Zanzucchi et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see

col. 4, line 35-54, indicating that the binding space, amplification space and detection space are inter connected to facilitate the flow of the fluids);

With regard to claims 71, Zanzucchi et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 9, line 15-33).

With regard to claim 72, Zanzucchi et al. teach a binding space for binding nucleic acids (see col. 9, line 15-33); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 10, line 6-42, col. 12, 42-60); and a sample transport mechanism which transports the sample and reagents through the space (see col. 12, line 42-60, indicating plurality of modules on a microlaboratory space for sample transport) Thus the disclosure of Zanzucchi et al. meets the limitations in the instant claims.

B. Claims 36-41, 68-73, 76-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Yasuda et al et al. (US 6,093,370).

Yasuda et al. teach an apparatus of 36, 70, 77-78, for detecting nucleic acids in a sample comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 22, col. 9, line 5-27, Fig. 7 indicates DNA binding space (731 and 733), also Fig. 21-23 indicate binding space (431));

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 9, line 27-36, col. 22, line 28-36, Fig. 7, indicates for amplification space (733), also see col. 17, line 11-27, Fig. 21-23, indicate amplification space (431);

(c) a detection space for detecting the nucleic acids (col. 9, line36-40, col. 22, line 37-43, Fig.7 indicates detection space and analysis (732), also see col. 17, line 35-53, Fig. 23-24 indicates detection space (401, 444)).

With regard to claims 37, 73, Yasuda et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 5-67, col. 10, line 23-53);

With regard to claims 39, 41, 76, Yasuda et al. teach that the amplification space comprises capillary space made up of glass (see col. 16, line 24-48, Fig. 20-21);

With regard to claim 40, 79, Yasuda et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal (chromium) layer (see col. 16, line 33-36, Fig. 20-21);

With regard to claim 68, Yasuda et al. teach an apparatus comprising capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (see col. 16, 29-48, Fig. 20, 21, indicating a capillary tube coated with a metal layer, col. 23, line 11-34);

With regard to claims 38, 69, Yasuda et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see col. 9, line 5-40, indicating that the binding space, amplification space and detection space are inter connected to facilitate the flow of the fluids);

With regard to claims 71, Yasuda et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 4, line 54-60, col. 9, line 5-40).

With regard to claim 72, Yasuda et al. teach that apparatus comprises a space for binding nucleic acids (se col. 4, line 54-60, col. 9, line 5-40); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 9, line 5-67, col. 10, line 23-53); and a sample transport mechanism which transports the sample and reagents through the space (see col. 9, line 5-40, indicating 711, 712, 713 for sample transport inlets for transporting sample and reagent solutions). Thus the disclosure of Yasuda meets the limitations in the instant claims.

C. Claims 68 is rejected under 35 U.S.C. 102(e) as being anticipated by Anderson (USPN. 6,126,804).

Andersen teaches an apparatus of claim 68, for amplifying nucleic acids comprising a capillary reaction vessel (see col. 7, line 30-67, col. 8, line 1-4) surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (electrically conductive coating made up of a metal, see col. 8, line 13-22). Accordingly the instant claim is anticipated by Andersen.

D. Claims 36-38, 69-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Fields (US 2003/0027203).

Fields teaches an apparatus of 36, 70, for detecting nucleic acids in a sample (see page 2, paragraph 0022) comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5);

(b) an amplification space for amplifying the nucleic acids (see fig. 6, paragraph 0063) wherein a part of amplification space is identical to a part of an amplification space (see Fig. 6, wherein the vial 420 is connected to amplification space by capillary tubes);

(c) a detection space for detecting the nucleic acids (see paragraphs 0063, indicates the amplified products are moved into device 425, for detection of amplified nucleic acid products).

With regard to claims 37, 73, Fields teaches that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see page 3, paragraphs 0031-0034);

With regard to claims 38, 69, Fields teaches that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see Fig. 1-3 and Fig. 6, wherein the detection space comprises a part of amplification space and a part of the binding space connected by a 3-way and four-way connecting tubes facilitating transport of sample and reagents, page 3, paragraph 0049-0054);

With regard to claims 71, Fields teaches that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see page 4, paragraph 0061).

With regard to claim 72, Fields teaches that the apparatus comprises a space for binding nucleic acids (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5); reagents for amplifying and detecting nucleic acids bound to the surface (see (see page 3, paragraphs 0031-0034); and a sample transport mechanism which transports the sample and reagent (see page 3, paragraph 0049-0054). Thus the disclosure of Fields meets the limitations in the instant claims.

Response to arguments

6. With regard to the rejection of claims 36-41 and 69-76 under 35 USC 102(b) as being anticipated by Zanzucchi et al. , Applicants' arguments are fully considered and found unpersuasive. Applicants argue that Zanzucchi et al. does not disclose a binding space that

includes at least part of an amplification spaceand assert that connecting channel (38) that connects the first well and a second well of Zannuachi et al. does not participate either in binding or in amplification.. The arguments are found not persuasive. First, Applicants misinterpreted the connecting chnnel as the part of binding and amplification space. In the above rejection Examiner clearly indicated that the binding space and the amplification space are connected by a connecting channel indicating that the binding space and amplification space are within the proximity to each other and there is no requirement to show that connecting channel participates in binding and amplification since connecting channel represents only to indicate that the amplification space and binding space are inter connected and represent that at least part of amplification space is within the binding space. The arguments regarding the claim 38 are fully considered and found unpersuasive. As discussed above the connection channel between amplification and detection space represent that at least part of the detection space is within the amplification and binding space. Thus the arguments based on connecting channel participating in amplification and detection are unpersuasive.

With regard to the claims 39 and 40, 72, Applicants argue that the wells are rectangular or square and are not surrounded by a capillary space or capillary reaction vessel as recited by the instant claims and argue that the metal layer does not surround the wells. The arguments are unpersuasive because the instant claims are in 'open' comprising format and the broader scope of the claims do not exclude the limitations taught by Zannuachi et al. further the instant claims 'at least part of the space" which clearly reads on spaces connected with each other as taught by Zannuachi et al. Further the instant claims recite at least one of the binding and the amplification space comprises a capillary space which clearly reads on connecting channels taught by

Zannuachi et al. therefore the arguments based on the shape of the wells and metal layer surrounding the wells is not persuasive. Further the new claim 79 recites that the metal layer is exterior of the vessel, which clearly is anticipated by Zannuachi et al. because the metal layer is exterior to the wells. taught by Zannuchi et al. For the reasons discussed above, Zannuchhi et al. does teach the limitations in the instant claims therefore the rejection is maintained herein and rewritten to include the new claim limitations.

7. With regard to the rejection of claims 36-41 and 68-76 under 35 USC 102(e) as being anticipated by Yasuda et al. Applicants' arguments are fully considered and found unpersuasive. Applicants argue that Yasuda et al. does not teach binding space aomprining at least part of the amplification space. Applicants also argue the col. 22, line 28-36 of Yasuda does not teach amplification space and assert the Yasuda et al. teach polynucleotide separation apparatus and Yasuda does not teach amplification and the arguments are based on selecting some specific parts cited by Examiner, ignoring the other cited columns by the Examiner. Applicant's arguments are found unpersuasive, because Applicants ignored other col. 9, line 5-36 cited by the Examiner, which clearly indicate s PCR amplification space. Further as discussed above the partitioned spaces read on binding, amplification and detection spaces and at least part of the space reads on connecting spacers between the solution spaces taught by Yasuda et al. With regard to the claims 38, 40, 68, 72 . Applicants argue that Yasuda et al does not teach heatable metal layer surrounding the vessel. Applicants ' arguments are found unpersuasive because the heatable metal layer taught by Yasuda is a glass capillary wherein the inner surface is coated with a stable oxide, thus the glass represents heatable metal layer which surround the reaction space wherein the inner surface is coated with an oxide for oxidation of metal.. There fore the

arguments re found unpersuasive and the rejection is maintained herein for unpersuasive arguments.

8. With regard to the rejection of claim 68 under 35 USC 102(e) as being anticipated by Andersen et al. Applicants arguments are found unpersuasive. Applicants argue that Andersson et al. does not teach capillary reaction vessel surrounded by a single heatable metal layer and argue that Andersson et al teach that the metal layer is applied to the inside and bottom of the portions of the PCR wells and is not applied to the cover plate and therefore does not teach limitations as recited in claim 68. Applicants' arguments are found unpersuasive because the instant claim do not require that the coating is on the cover plate rather it recites capillary vessel surrounded by single heatable layer as discussed in the rejection the electrically conductive material does teach asingel metal layer surrounding the capillary space and therefore the rejection is maintained.

9. With regard to the rejection of claims 36-38, 69-73 under 35 USC 102(e) as being anticipated by Fields Applicants' arguments are fully considered and found unpersuasive. Applicants basically argue that the connecting aspects taught by Fields do not read on at least part of the space of binding or amplification or detection spaces. Applicant's arguments re found unpersuasive because the three-way connecting valves unite all the tree spaces and thus the limitation that 'at least part of the space' does read on the teaching of Fields and therefore Fields does anticipate the instant claims. Examiner notes that the connecting valves clearly connects all the three spaces and thus the limitation at least part of clearly anticipate the e instant claims. With regard to heatable metal layer the cited paragraphs 0063, 0027 indicates heating means and

thermal cycling device, which are self explanatory that the device comprises heatable metal layer. Therefore the rejection is maintained herein.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637

Conclusion

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